

HOUSE No. 2683

By Ms. Jehlen of Somerville, petition of Patricia D. Jehlen and others relative to establishing a prescription drug pricing program. Public Health.

The Commonwealth of Massachusetts

PETITION OF:

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In the Year Two Thousand and Five.

AN ACT ESTABLISHING THE MASSACHUSETTS PRESCRIPTION DRUG FAIR
PRICING PROGRAM.

*Be it enacted by the Senate and House of Representatives in General
Court assembled, and by the authority of the same, as follows:*

1 SECTION 1. Chapter 118E of the General Laws is hereby
2 amended by inserting after section 12 the following sections:

3 Section 12A. Consumer Protection Rules; Prior Authorization
4 of Prescription Drugs.

5 (a) Any prior authorization process required by the division
6 before it authorizes coverage for a prescription drug shall comply
7 with the consumer protections in this section and with 42 U.S.C.
8 section 1396r-8(d).

9 (b) Coverage for a prescription drug that is not covered by the
10 division without prior authorization shall be authorized if a
11 patient's health care provider certifies, in a manner determined by
12 the division, that:

13 (i) the drug is medically necessary; and

14 (ii) in the case of a prescription drug that is not the preferred
15 choice in a therapeutic category on the preferred drug list,

16 (A) the preferred choice has not been effective, or with reason-
17 able certainty is not expected to be effective in treating the
18 patient's condition; or

19 (B) the preferred choice causes or is reasonably expected to
20 cause adverse or harmful reactions in the patient.

21 (c) The prescriber's certification concerning whether a partic-
22 ular drug has been ineffective, is expected to be ineffective in
23 treating the patient, or is expected to cause an adverse or harmful
24 reaction shall be final.

25 (d) (1) The division's prior authorization process shall be
26 designed to minimize administrative burdens on prescribers, phar-
27 macists, and consumers.

28 (2) The prior authorization process shall ensure real-time
29 receipt of requests, by telephone, voice mail, facsimile, electronic
30 transmission, or mail on a 24-hour basis, seven days a week.

31 (3) The prior authorization process shall provide an in-person
32 response to emergency requests by a prescriber with telephone
33 answering queues that do not exceed 10 minutes.

34 (4) Any request for authorization or approval of a drug that the
35 prescriber indicates, including the clinical reasons for the request,
36 is for an emergency or urgent condition shall be responded to in
37 no more than 4 hours from the time the program or participating
38 health benefit plan receives the request.

39 (5) In emergency circumstances, or if the response to a request
40 for prior authorization is not provided within the time period
41 established in subdivision (4) of this subsection, a 72-hour supply
42 of the drug prescribed shall be deemed to be authorized by the
43 program or the participating health benefit plan, provided it is a
44 prescription drug approved by the United States Food and Drug
45 Administration, and provided, for drugs dispensed to a Medicaid
46 beneficiary, it is subject to a rebate agreement with the Centers for
47 Medicare and Medicaid Services.

48 (6) The division shall provide to participating providers a prior
49 authorization request form designed to permit the prescriber to
50 make prior authorization requests in advance of the need to fill the
51 prescription, and designed to be completed without unnecessary
52 delay. The form shall be capable of being stamped with informa-
53 tion relating to the participating provider and, if feasible, at least
54 one form capable of being copied shall contain known patient
55 information.

56 (e) The division's prior authorization process shall require that
57 the prescriber, not the pharmacy, request a prior authorization
58 exception to the requirements of this section. The division may
59 exempt a prescriber from the need to secure prior authorization for
60 a specific drug category if the division determines that the pre-
61 scriber has written a minimum number of scripts in that category,
62 and the prescriber prescribes prescription drugs on the preferred
63 drug list at or above the minimum threshold for that category.

64 (f) If the patient is denied authorization of coverage, the denial
65 shall be subject to an administrative fair hearing and to all rights
66 under section 14 of chapter 30A of the General Laws.

67 (g) The division shall, using bulletins, manuals, notices or other
68 appropriate means, educate prescribers and pharmacists who treat
69 MassHealth patients about the requirements of the prior authoriza-
70 tion process, including the obligations of providers and pharma-
71 cists and the rights of consumers.

72 Section 12B. Supplemental Rebates.

73 (a) The commissioner, separately or in concert with the autho-
74 rized representatives of any health benefit plan participating in the
75 prescription drug fair pricing program established by chapter
76 118H, shall use the division's preferred drug list of prescription
77 drugs covered without a prior authorization requirement to nego-
78 tiate with pharmaceutical companies for the payment to the com-
79 missioner of supplemental rebates or price discounts for
80 Medicaid. The commissioner may also use the preferred drug list
81 to negotiate for the payment of rebates or price discounts in con-
82 nection with drugs covered under any other health benefit plan
83 within or outside this state participating in the prescription drug
84 fair pricing program established by chapter 118H. Such negotia-
85 tions and any subsequent agreement shall comply with the provi-
86 sions of 42 U.S.C. section 1396r-8. The program established by
87 chapter 118H, or such portions of the program as the commis-
88 sioner shall designate, shall constitute a state pharmaceutical
89 assistance program under 42 U.S.C. section 1396r-8(c)(1)(C).
90 The provisions of this section do not authorize agreements with
91 pharmaceutical manufacturers whereby financial support for med-
92 ical services covered by the Medicaid program is accepted as con-
93 sideration for placement of one or more prescription drugs on the
94 preferred drug list or for excluding a drug from any prior autho-
95 rization requirement.

96 (b) The commissioner shall provide quarterly reports on the
97 progress of negotiating supplemental rebates pursuant to this
98 section to the joint committee on health care and the house and
99 senate committees on ways and means. By September 1, 2003,
100 the commissioner shall provide with the next occurring quarterly
101 report a cost benefit analysis of alternative negotiation strategies,
102 including strategies used by the state Medicaid agencies in states
103 of Florida and Michigan to secure supplemental rebates and any
104 other alternative negotiation strategy that might secure lower net
105 prescription drug costs.

106 (c) The commissioner shall prohibit the public disclosure of
107 information revealing company-identifiable trade secrets obtained
108 by the department, and by any officer, employee or contractor of
109 the department in the course of negotiations conducted pursuant to
110 this section. Such confidential information shall be exempt from
111 public disclosure.

112 Section 12C. Discount Program Waiver.

113 (a) The division shall seek a prescription drug discount pro-
114 gram waiver from the Centers for Medicare and Medicaid Serv-
115 ices pursuant to section 1115(a) of the Social Security Act. The
116 prescription drug discount program shall provide eligible individ-
117 uals with a financial subsidy for prescription drugs equal to the
118 average rebate paid to the Medicaid program by pharmaceutical
119 manufacturers. Eligible individuals shall include Medicare-eli-
120 gible individuals whose financial eligibility exceeds 188 per cent
121 of federal poverty level and who do not have an insurance policy
122 that covers drugs and other individuals whose financial eligibility
123 does not exceed 300 per cent of the federal poverty level who do
124 not have an insurance program that includes a prescription drug
125 benefit.

126 (b) The division may establish, as part of the discount program,
127 an annual enrollment fee. Subject to appropriation, the division
128 shall make a payment of at least 2 percent of the cost of each pre-
129 scription or refill dispensed to individuals enrolled in the program.

130 (c) In implementing the program, the division may contract
131 with a nonprofit corporation or other entity to administer the pro-
132 gram. Such corporation or entity shall agree to assist individuals
133 enrolled in the program to access other free or discount prescrip-
134 tion drug programs offered by private entities, including pharma-
135 ceutical manufacturers.

136 (d) The division shall report to the house and senate committees
137 on ways and means and the joint committee on health care, not
138 later than 60 days after the effective date of this section, on the
139 division's progress in implementing this section and shall report
140 every 90 days thereafter on its progress in obtaining the waiver to
141 those committees.

1 SECTION 2. The General Laws are hereby amended by
2 inserting the following new chapter:

3

CHAPTER 118H.

4

The Massachusetts Prescription Drug

5

Fair Pricing Program.

6 Section 1. Program Established.

7 (a) There is hereby established a program to reduce the cost to
8 the Commonwealth of providing prescription drugs to its citizens
9 while maintaining high quality in prescription drug therapies. The
10 program shall include, but shall not be limited to, the following
11 components:

12 (1) the development and use of a statewide, uniform preferred
13 list of covered prescription drugs that identifies preferred choices
14 within therapeutic classes for particular diseases and conditions,
15 including generic and therapeutic equivalents;

16 (2) the creation of a single purchasing unit for the purchase of
17 prescription drugs by the commonwealth;

18 (3) the use of strategies to negotiate with pharmaceutical manu-
19 facturers to lower the cost of prescription drugs for program par-
20 ticipants, including a supplemental rebate program;

21 (4) the development of educational programs, including a coun-
22 terdetailing program, designed to provide information and educa-
23 tion on the therapeutic and cost-effective utilization of
24 prescription drugs to consumers, physicians, pharmacists and
25 other health care professionals authorized to prescribe and dis-
26 pense prescription drugs;

27 (5) the utilization of any available cost containment tools that
28 meet program objectives by reducing the cost to the common-
29 wealth of obtaining and providing prescription drugs, including
30 clinical management tools, utilization review procedures, a prior
31 authorization review process, duplicate prescription monitoring,
32 and refill and supply controls;

33 (6) the observance of consumer protection rules to maintain
34 high quality in prescription drug therapies and to protect access to
35 needed prescriptions; and

36 (7) the operation of a discount program to provide the benefit
37 of negotiated price discounts to uninsured citizens.

38 (b) The following state agencies shall participate in the pro-
39 gram authorized in this chapter, to the extent permitted by federal
40 law:

41 (1) the division of medical assistance;
42 (2) the executive office of elder affairs;
43 (3) the group insurance commission;
44 (4) the department of public health;
45 (5) the department of mental health;
46 (6) the department of mental retardation;
47 (7) the department of correction; and
48 (8) the division of employment and training.
49 (c) Any other public or private health benefit plan that pur-
50 chases prescription drugs may elect to participate in all or portions
51 of the program.

52 Section 2. Bulk Purchasing Agreements.

53 (a) State agencies and other participants in the program shall
54 act as a single purchasing unit for the negotiation of a contract to
55 purchase prescription drugs on behalf of the commonwealth.

56 (b) The prescription drug procurement unit created by section
57 62 of chapter 177 of the Acts of 2001 shall implement all or part
58 of the program to the extent permitted by federal law. The secre-
59 tary of the executive office of elder affairs, the commissioner of
60 the group insurance commission and the commissioners of the
61 departments of public health, mental health and mental retardation
62 may renegotiate or amend existing contracts for the purchase of
63 prescription drugs, including a contract made in conformance with
64 said section 62, if such renegotiation or amendment is necessary
65 to implement all or part of the program and will be of economic
66 benefit to the health benefit plans subject to such contracts, and to
67 the beneficiaries of such plans. Any renegotiated or substituted
68 contract shall be designed to improve the overall quality of inte-
69 grated health care services provided to beneficiaries of such plans.

70 Section 3. Pharmaceutical Benefits Manager.

71 (a) State agencies and other participants in the program may
72 contract with a third party pharmacy benefit manager to assist in
73 implementation of the program. Such pharmacy benefit manager
74 shall be a non-profit corporation with expertise in the manage-
75 ment of pharmacy benefits.

76 (b) No contract shall be signed with a pharmacy benefit man-
77 ager unless the pharmacy benefit manager has agreed to disclose
78 to the commonwealth, in a manner that preserves the confiden-
79 tiality of any proprietary information:

- 80 (1) operating statements of the pharmacy benefit manager;
- 81 (2) total revenue attributable to pharmaceutical manufacturer
- 82 rebates and total revenue not attributable to pharmaceutical manu-
- 83 facturer rebates;
- 84 (3) all sources of rebate revenue and non-rebate revenue, and
- 85 amounts of revenue from such sources;
- 86 (4) rebate management fees collected;
- 87 (5) the terms and conditions of any contract with any subcon-
- 88 tractor, including contracts with the pharmacy benefit manager's
- 89 pharmacy network; and
- 90 (6) the terms and conditions of any sale or exchange of pre-
- 91 scription drug data concerning beneficiaries or the prescribing
- 92 practices of the providers.
- 93 (c) No contract shall be signed with a pharmacy benefit man-
- 94 ager that has entered into an agreement or engaged in one or more
- 95 of the following practices unless a majority of state agency partic-
- 96 ipants in the program determines, after consideration of all rele-
- 97 vant circumstances, that such agreement or practice furthers the
- 98 financial interests of the commonwealth, and does not adversely
- 99 affect the financial or medical interests of beneficiaries:
- 100 (1) any agreement with a pharmaceutical manufacturer to favor
- 101 the manufacturer's products over a competitor's products, or to
- 102 switch the drug prescribed by the patient's health care provider
- 103 with a drug agreed to by the pharmacy benefit manager and the
- 104 manufacturer;
- 105 (2) any agreement with a pharmaceutical manufacturer to share
- 106 manufacturer rebates and discounts with the pharmacy benefit
- 107 manager, or to pay soft money, so-called, or other economic bene-
- 108 fits to the pharmacy benefit manager;
- 109 (3) any agreement to share revenue with a mail order or internet
- 110 pharmacy company;
- 111 (4) any agreement or practice to bill the commonwealth's health
- 112 benefit plans for prescription drugs at a cost higher than the phar-
- 113 macy benefit manager pays the pharmacy; or
- 114 (5) any agreement to sell prescription drug data concerning
- 115 beneficiaries, or data concerning the prescribing practices of
- 116 health care providers.
- 117 Section 4. Cost Containment Tools.
- 118 (a) The program shall include the following components:

119 (1) A preferred list of covered prescription drugs that identifies
120 preferred choices within therapeutic classes for particular diseases
121 and conditions, including generic alternatives.

122 (i) The preferred drug list shall be implemented as a uniform,
123 statewide, preferred drug list for use by state agencies partici-
124 pating in the program and health benefit plans in the Common-
125 wealth shall be encouraged to participate in the program.

126 (ii) The program may utilize the MassHealth Drug List devel-
127 oped by the division of medical assistance as its preferred drug
128 list. In order to assist the state agencies participating in the pro-
129 gram with the development, modification and timely revision of
130 the preferred drug list, such agencies shall appoint a Drug List
131 Review Board. The board may be comprised in whole or in part of
132 representatives of state agencies, including the Drug Use Board
133 established by the division of medical assistance pursuant to fed-
134 eral law, or may be established by contract with a public or private
135 non-profit organization. The board shall:

136 (A) make recommendations for the adoption and maintenance
137 of the preferred drug list based upon considerations of clinical
138 efficacy, safety, and cost-effectiveness;

139 (B) meet at least quarterly;

140 (C) to the extent feasible, review all drug classes included in
141 the preferred drug list at least every 12 months, and recommend
142 additions to or deletions from the preferred drug list;.

143 (D) establish board procedures for the timely review of pre-
144 scription drugs newly approved by the federal Food and Drug
145 Administration, including procedures for the review of newly
146 approved prescription drugs in emergency circumstances,
147 including early refill review standards, a prior authorization
148 review process, duplicate prescription monitoring, and quality and
149 supply controls;

150 (E) encourage health benefit plans to implement the preferred
151 drug list as a uniform, statewide preferred drug list by inviting the
152 representatives of each health benefit plan providing prescription
153 drug coverage to residents of the commonwealth to participate as
154 observers or nonvoting members in the commissioners drug uti-
155 lization review board, and by inviting such plans to use the pre-
156 ferred drug list in connection with the plans' prescription drug
157 coverage.

158 (iii) Members of the board shall receive per diem compensation
159 and reimbursement of board related expenses. The board shall
160 consult with a preferred drug list advisory group which shall
161 include 1 designee of the commissioner of mental health; 1
162 designee of the commissioner of public health; 1 designee of the
163 secretary of the executive office of elder affairs; 1 physician with
164 experience treating MassHealth patients; 1 practicing pediatrician
165 with experience treating MassHealth patients; 1 practicing phar-
166 macist with experience serving MassHealth patients; 1 pharmacol-
167 ogist with expertise in psychiatric drugs; 1 representative of a
168 senior citizens advocacy group; 1 representative of a disability
169 advocacy group; and 1 representative of a statewide advocacy
170 group representing the interests of MassHealth members.

171 (2) A series of educational programs including a counterde-
172 tailing program, designed to provide information and education on
173 the therapeutic and cost effective utilization of prescription drugs
174 to consumers, physicians, pharmacists and other health care pro-
175 fessionals authorized to prescribe and dispense prescription drugs.

176 (3) Consideration of alternative pricing mechanisms including
177 consideration of using maximum allowable cost pricing for
178 generic and other prescription drugs.

179 (4) Consideration of alternative coverage terms, including con-
180 sideration of providing coverage of over-the-counter drugs where
181 cost-effective in comparison to prescription drugs, and authorizing
182 coverage of dosages capable of permitting the consumer to split
183 each pill if cost-effective and medically appropriate for the con-
184 sumer.

185 (5) Development of a simple, uniform prescription form,
186 designed to implement the preferred drug list, and to enable pre-
187 scribers and consumers to request an exception to the preferred
188 drug list choice with a minimum of cost and time to prescribers,
189 pharmacists and consumers.

190 Section 5. Consumer Protection Rules.

191 (a) The program shall authorize pharmacy benefit coverage
192 when a patient's health care provider prescribes a prescription
193 drug not on the preferred drug list, if a patient's health care
194 provider certifies that:

195 (i) the drug is medically necessary; and

196 (ii) in the case of a prescription drug that is not the preferred
197 choice in a therapeutic category on the preferred drug list,

198 (A) the preferred choice has not been effective, or with reason-
199 able certainty is not expected to be effective in treating the
200 patient's condition; or

201 (B) the preferred choice causes or is reasonably expected to
202 cause adverse or harmful reactions in the patient.

203 (b) The prescriber's certification concerning whether a partic-
204 ular drug has been ineffective, is expected to be ineffective in
205 treating the patient, or is expected to cause an adverse or harmful
206 reaction shall be final.

207 (c) The program shall authorize coverage notwithstanding any
208 prior authorization requirement if the patient agrees to pay any
209 additional cost in excess of the benefits provided by the patient's
210 health benefit plan. The provisions of this paragraph shall not
211 apply in circumstances in which their application is inconsistent
212 with federal Medicaid laws and regulations. The provisions of
213 this paragraph shall not affect implementation by a participating
214 health benefit plan of tiered co-payments or other similar cost
215 sharing systems.

216 (d) The program or any participating health benefit plan shall
217 provide information on how prescribers, pharmacists, beneficia-
218 ries, and other interested parties can obtain a copy of the preferred
219 drug list, whether any change has been made to the preferred drug
220 list since it was last issued, and the process by which exceptions
221 to the preferred list may be made.

222 (e)(1) The program's prior authorization process shall be
223 designed to minimize administrative burdens on prescribers, phar-
224 macists, and consumers.

225 (2) The prior authorization process shall ensure real-time
226 receipt of requests, by telephone, voice mail, facsimile, electronic
227 transmission, or mail on a 24-hour basis, seven days a week.

228 (3) The prior authorization process shall provide an in-person
229 response to emergency requests by a prescriber with telephone
230 answering queues that do not exceed 10 minutes.

231 (4) Any request for authorization or approval of a drug that the
232 prescriber indicates, including the clinical reasons for the request,
233 is for an emergency or urgent condition shall be responded to in
234 no more than 4 hours from the time the program or participating
235 health benefit plan receives the request.

236 (5) In emergency circumstances, or if the response to a request
237 for prior authorization is not provided within the time period
238 established in subdivision (4) of this subsection, a 72-hour supply
239 of the drug prescribed shall be deemed to be authorized by the
240 program or the participating health benefit plan, provided it is a
241 prescription drug approved by the United States Food and Drug
242 Administration, and provided, for drugs dispensed to a Medicaid
243 beneficiary, it is subject to a rebate agreement with the Centers for
244 Medicare and Medicaid Services.

245 (6) The program or participating plan shall provide to partici-
246 pating providers a prior authorization request form designed to
247 permit the prescriber to make prior authorization requests in
248 advance of the need to fill the prescription, and designed to be
249 completed without unnecessary delay. The form shall be capable
250 of being stamped with information relating to the participating
251 provider and, if feasible, at least one form capable of being copied
252 shall contain known patient information.

253 (f) The program's prior authorization process shall require that
254 the prescriber, not the pharmacy, request a prior authorization
255 exception to the requirements of this section. The program may
256 exempt a prescriber from the need to secure prior authorization for
257 a specific drug category if the program determines that the pre-
258 scriber has written a minimum number of scripts in that category,
259 and the prescriber prescribes prescription drugs on the preferred
260 drug list at or above the minimum threshold for that category.

261 (g) If the patient is denied authorization of coverage, the denial
262 shall be subject to an administrative fair hearing and to all rights
263 under section 14 of chapter 30A of the general laws.

264 Section 6. Discount Card Program.

265 (a) The commissioner of health and human services or another
266 commissioner of a participating state agency designated by pro-
267 gram participants shall implement a pharmacy discount plan, to be
268 known as the Healthy Massachusetts Discount Card Plan, for resi-
269 dents without adequate coverage for prescription drugs. As used
270 in this section, a resident without adequate coverage means a resi-
271 dent of the commonwealth with no insurance coverage for pre-
272 scription drugs or with coverage for which the annual maximum
273 coverage limit under his health benefit plan has been reached.
274 Such plan shall establish a system through which residents

275 without adequate coverage are able to take advantage of dis-
276 counted prices for prescription drugs negotiated pursuant to this
277 chapter. Such commissioner shall implement the pharmacy dis-
278 count program authorized by this section without any financial
279 contribution by the state, and may establish an enrollment fee in
280 such amount as is necessary to support the administrative costs of
281 the plan. The plan shall be designed to work cooperatively with
282 other state prescription drug assistance programs, including any
283 program created pursuant to a discount program waiver granted by
284 the Centers for Medicare and Medicaid Services to the division of
285 medical assistance. Such commissioner may contract with a non-
286 profit corporation or other entity to administer the program. Such
287 corporation or entity shall agree to assist individuals eligible for
288 the program to access other free or discount prescription drug pro-
289 grams offered by private entities, including pharmaceutical manu-
290 facturers.

291 Section 7. Reporting and Legislative Oversight.

292 (a) The commissioner of health and human services or another
293 commissioner of a participating state agency designated by pro-
294 gram participants shall report quarterly to the joint committee on
295 health care and the house and senate committees on ways and
296 means on progress of the program in implementing a single state
297 purchasing unit for prescription drugs pursuant to section 2. The
298 report shall provide a status report on the formation of or opera-
299 tion of the contract negotiated pursuant to section 2, and shall
300 identify any barriers to full implementation of section 2 and rec-
301 ommend any changes to the program or other legislative changes
302 advisable to eliminate such barriers. The report shall also report
303 on the program's progress in securing the participation of other
304 health benefit plans with the commonwealth by means of joint
305 purchasing agreements to enhance the commonwealth's pur-
306 chasing power.

307 (b) Each year for the duration of the pharmacy benefit manager
308 contract pursuant to section 3, the commissioner of health and
309 human services or another commissioner of a participating state
310 agency designated by program participants shall provide a status
311 report on the contract and the operations of the pharmacy benefit
312 manager to the joint committee on health care and the house and
313 senate committees on ways and means. The report shall include:

314 (1) a description of the activities of the pharmacy benefit
315 manager;

316 (2) an analysis of the success of the pharmacy benefit manager
317 in achieving each of the department's public policy goals, together
318 with the pharmacy benefit manager's report of its activities and
319 achievements;

320 (3) an assessment, based upon information learned in contracting
321 with the pharmacy benefits manager, of administrative costs relating
322 to prescription drug benefits in the Medicaid program and the Pre-
323 scription Advantage program established pursuant to section 39 of
324 chapter 19A, including any recommendations for increasing the
325 administrative efficiency of such programs;

326 (4) any recommendations for enhancing the benefits of or mini-
327 mizing inefficiencies of the pharmacy benefit manager contract or
328 advancing the commonwealth's public policy goals relating to
329 pharmaceutical costs, quality and access;

330 (5) a fiscal report on the costs and savings to the common-
331 wealth of the pharmacy benefit manager contract, including the
332 information disclosed pursuant to paragraph (b) of section 3, in a
333 manner that preserves the confidentiality of any proprietary infor-
334 mation; and

335 (6) if the pharmacy benefit manager engages in any of the
336 activities described in paragraph (c) of section 3, an explanation
337 of the reasons for finding that such agreement or practice furthers
338 the financial interests of the commonwealth, and does not
339 adversely affect the financial or medical interests of beneficiaries.

340 (c) The commissioner of health and human services or another
341 commissioner of a participating state agency designated by pro-
342 gram participants shall report quarterly to the joint committee on
343 health care and the house and senate committees on ways and
344 means concerning the cost containment aspects of the program
345 undertaken pursuant to section 4. Such report shall include:

346 (1) a copy of the preferred drug list, an explanation of the list, a
347 summary of the operation of the prior authorization process or any
348 other cost savings measures instituted as a part of the list, and
349 an estimate of expected cost savings as a result of the preferred
350 drug list;

351 (2) a description of the efforts undertaken to educate consumers
352 and health care providers about the preferred drug list and the pro-
353 gram's utilization review procedures;

354 (3) a description of the efforts undertaken to establish programs
355 to educate health care providers about the costs of prescribing pat-
356 terns, including counterdetailing programs;

357 (4) a report of other cost containment strategies undertaken,
358 including, but not limited to, alternative pricing mechanisms and
359 alternative coverage terms, the expected savings from such strate-
360 gies, and the effect of such strategies on access to prescription
361 drugs for consumers; and

362 (5) a status report on the development of a uniform prescription
363 form and any barriers to such development.

364 (d) The joint committee on health care shall closely monitor
365 implementation of the program, including the preferred drug list
366 and utilization review procedures, to ensure that the consumer
367 protection standards are not diminished as a result of imple-
368 menting the preferred drug list and the utilization review proce-
369 dures, including any unnecessary delay in access to appropriate
370 medications. Such joint committee shall, by means of an over-
371 sight hearing or otherwise, ensure that all affected interests,
372 including consumers, health care providers, pharmacists and
373 others with pharmaceutical expertise have an opportunity to com-
374 ment on the operation of the program, the preferred drug list, and
375 other procedural aspects of the program.

1 SECTION 3. The General Laws are hereby amended by adding
2 after chapter 268B the following chapter.—

3

CHAPTER 268C.

4

Physician and Pharmaceutical Manufacturer Conduct.

5 Section 1. As used in this chapter, the following words shall
6 have the following meanings:—

7 “Gift”, a payment, entertainment, subscription, advance, serv-
8 ices or anything of value, unless consideration of equal or greater
9 value is received. “Gift” shall not include a commercially reason-
10 able loan made in the ordinary course of business, anything of
11 value received by inheritance, a gift received from a member of
12 the reporting person’s immediate family or from a relative within
13 the third degree of consanguinity of the reporting person or of the
14 reporting person’s spouse or from the spouse of any such relative,

15 or prescription drugs provided to a physician solely and exclu-
16 sively for use by the physician's patients.

17 "Immediate family", a spouse and any dependent children
18 residing in the reporting person's household.

19 "Medical device", an instrument, apparatus, implement,
20 machine, contrivance, implant, in vitro reagent, or other similar or
21 related article, including any component, part, or accessory, which
22 is:

23 (1) recognized in the official National Formulary, or the United
24 States Pharmacopeia, or any supplement to them,

25 (2) intended for use in the diagnosis of disease or other condi-
26 tions, or in the cure, mitigation, treatment, or prevention of dis-
27 ease, in man or other animals, or

28 (3) intended to affect the structure or any function of the body
29 of man or other animals, and which does not achieve its primary
30 intended purposes through chemical action within or on the body
31 of man or other animals and which is not dependent upon being
32 metabolized for the achievement of its primary intended purposes.

33 "Person", a business, individual, corporation, union, associa-
34 tion, firm, partnership, committee, or other organization or group
35 of persons.

36 "Pharmaceutical marketer", a person who, while employed by
37 or under contract to represent a pharmaceutical manufacturing
38 company, engages in pharmaceutical detailing, promotional activi-
39 ties, or other marketing of prescription drugs in this state to any
40 physician, hospital, nursing home, pharmacist, health benefit plan
41 administrator, or any other person authorized to prescribe, dis-
42 pense, or purchase prescription drugs. The term does not include
43 a wholesale drug distributor licensed under section 36A, a repre-
44 sentative of such a distributor who promotes or otherwise markets
45 the services of the wholesale drug distributor in connection with a
46 prescription drug, or a retail pharmacist registered under section
47 37 if such person is not engaging in such practices under contract
48 with a manufacturing company.

49 "Pharmaceutical manufacturing company", any entity which is
50 engaged in the production, preparation, propagation, com-
51 pounding, conversion, or processing of prescription drugs, either
52 directly or indirectly by extraction from substances of natural
53 origin, or independently by means of chemical synthesis, or by a

54 combination of extraction and chemical synthesis, or any entity
55 engaged in the packaging, repackaging, labeling, relabeling, or
56 distribution of prescription drugs. The term does not include a
57 wholesale drug distributor licensed under section 36A or a retail
58 pharmacist registered under section 37.

59 “Pharmaceutical manufacturer agent”, a pharmaceutical mar-
60 keter or any other person who for compensation or reward does
61 any act to promote, oppose or influence the prescribing of a par-
62 ticular prescription drug or medical device or category of pre-
63 scription drugs or medical devices. The term shall not include a
64 licensed pharmacist, licensed physician or any other licensed
65 health care professional with authority to prescribe prescription
66 drugs who is acting within the ordinary scope of the practice for
67 which he is licensed.

68 “Physician”, a person licensed to practice medicine by the
69 board of medicine pursuant to section 2 of chapter 112.

70 “Prescription drugs”, any and all drugs upon which the manu-
71 facturer or distributor has placed or must, in compliance with fed-
72 eral law and regulations, place the following or a comparable
73 warning: “Caution federal law prohibits dispensing without pre-
74 scription.”

75 Section 2. No pharmaceutical manufacturer agent shall know-
76 ingly and willfully offer or give to a physician or a member of a
77 physician’s immediate family, and no physician shall knowingly
78 and willfully solicit or accept from any pharmaceutical manufac-
79 turer, gifts of any value at any time.

80 Section 3. A person who violates this section shall be punished
81 by a fine of not more than \$5,000 or by imprisonment for not
82 more than 2 years, or both.

1 SECTION 4. The commissioner of the division of medical
2 assistance, the secretary of the executive office of elder affairs,
3 the commissioner of the group insurance commission and the
4 commissioners of state agencies participating in the Massachu-
5 setts prescription drug fair pricing program established by chap-
6 ter 118H of the general laws shall take all steps necessary to
7 enable the commonwealth to participate in joint prescription drug
8 purchasing agreements with other states and other health benefit
9 plans. Such steps shall include:

10 (1) Active collaboration with the National Legislative Associa-
11 tion on Prescription Drug Prices in the Association's efforts;

12 (2) Active collaboration with the Pharmacy RFP Issuing States
13 Initiative, so-called, organized by the West Virginia Public
14 Employees Insurance Agency; and

15 (3) The execution of any joint purchasing agreements or other
16 contracts with any health benefit plan or organization within or
17 outside the state which such commissioners determines will lower
18 the cost of prescription drugs for the commonwealth and its citi-
19 zens while maintaining high quality in prescription drug therapies.

1 SECTION 5. (a) The General Court finds that the National Leg-
2 islative Association on Prescription Drug Prices is a nonprofit
3 organization of legislators formed for the purpose of making pre-
4 scription drugs more affordable and accessible to citizens of the
5 member states, including the commonwealth. The General Court
6 further finds that the activities of the Association provide a public
7 benefit to the people of the commonwealth.

8 (b) Three members of the senate, including one member of the
9 minority party, shall be appointed directors of the Association by
10 the senate president, and three members of the house of represen-
11 tatives, including one member of the minority party, shall be
12 appointed directors of the Association by the speaker of the house.
13 Directors so appointed shall serve until new members are
14 appointed.

15 (c) The directors of the Association shall report to the house
16 and senate committees on ways and means and the joint commit-
17 tees on health care and insurance on or before January 1 of each
18 year with a summary of the activities of the Association, and any
19 findings and recommendations for making prescription drugs
20 more affordable and accessible to citizens of the commonwealth.